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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/504,393 02/15/00 BACHMANN

H 20347/111656

EXAMINER

HM22/0131

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PAK.Y

ART UNIT	PAPER NUMBER
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1652

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DATE MAILED:

01/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/504,393

Applicant(s)

BACHMANN ET AL.

Examiner

Yong Pak

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 16-18 and 33 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28-32 and 34-36 is/are allowed.
- 6) ☒ Claim(s) 6-15 and 19-27 is/are rejected.
- 7) ☒ Claim(s) 6, 8-9 and 19 is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on July 15, 2000 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

The instant application as originally filed contains two claims 27. In accordance with 37 CFR § 1.126, starting at the second occurrence of claims 27, claims have been renumbered 28-36 with dependencies changed accordingly. The new numbers have been used hereinafter.

Claims 1-36 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5 and 33 drawn to dioxygenase and a method of use thereof, classified in class 435, subclass 25.
- II. Claims 6-15, 19-32, and 34-36, drawn to DNA encoding dioxygenase and vector encoding said DNA, host cell comprising thereof, antisense RNA and primer, probe and test kit for amplifying/detection of said DNA, classified in class 435, subclass 6.
- III. Claims 16-17, drawn to antibody against dioxygenase and method of using antibody, classified in class, 530 subclass 387.9.
- IV. Claim 18, drawn to a method of producing Vitamin A, classified in class 568, subclass 824.

The inventions are distinct, each from the other because of the following reasons:

The protein of Invention I is related to the nucleic acids of Invention II by virtue of encoding the same. Although the DNA molecule and protein are related since the DNA encodes the claimed protein, they are distinct inventions. The two are physically and functionally distinct chemical entities. Also, the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from a natural source. Furthermore, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The methods of Invention II and the polypeptide of Invention I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed maybe isolated form a natural source.

The enzyme of Invention I is related to the antibodies of Invention III by virtue of being cognate antigen, necessary for the production of antibodies. Although the polypeptide and antibody are related due to necessary strike complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities. The structure of antibody is unpredictable from the structure of the protein. Also because the enzyme can be

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used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the cognate receptor of the protein (as the protein is itself a ligand), or in assays for the identification of agonists or antagonists of the receptor protein.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Vitamin A can be isolated from a natural source. Furthermore, dioxygenase can be used in production of antibodies.

The DNA of Invention II is distinct from the antibody of Invention III. DNA and antibody are physically and functionally distinct chemical entities. Also the methods of Inventions II-IV are patentably distinct as employing different products. Invention II uses DNA encoding dioxygenase, Invention III uses an antibody and Invention IV uses dioxygenase.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Hooper on December 29, 2000 a provisional election was made with traverse to prosecute the invention of II, claims 6-15, 19-32 and 34-36. Applicant in replying to this Office action must make affirmation of this election. Claims 1-5, 16-18, and 33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

Drawings filed concurrently with the application has been objected by the Draftsman. Please refer to the attached PTO-948 form for details.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

Claims 6 and 19 are objected to as being dependent upon a non-elected base claim. However for the interest of a compact prosecution, claims 6 and 19 have been interpreted with the limitations of claim 1.

Claims 8-9 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants are required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 8-9 ultimately depend on claim 1, which recites a DNA encoding a polypeptide having β,β -carotene 15,15'-dioxygenase activity and being 60% homologous to SEQ ID NO:1. Claims 8-9 do not include the limitation of the claim on which it depends because a DNA fragment of 20 bases cannot encode a polypeptide that is more than 60% identical to SEQ ID NO:1.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 7, if correctly read as ultimately depending on claim 1, includes only a fragment of SEQ ID NO:2 that is enzymatically active and encodes a sequence that is 60% homologous to SEQ ID NO:1. Such fragment must be about 1800 bases or 60% of 3111 bases of SEQ ID NO:2. However, claims 8 and 9 recite 20 and 30 bases, respectively, and the structural limitations in these two claims amount to about 1 % (see rejection under 35 U.S.C. § 112, second paragraph for vagueness of claims 8-9). Therefore, these claims are drawn to a genus of enzymes described by its function. Applicants fail to describe any representative species by identifying characteristics or structural properties other than the functionality of being a β,β -carotene 15,15'-dioxygenase oxidase.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 7-9.

Claims 6-15 and 19-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA molecules encoding SEQ ID NO: 1, does not reasonably provide enablement for any DNA or DNA fragments encoding a β,β -carotene 15,15'-dioxygenase having 60% homology to SEQ ID NO:1 or comprising 20 or 30 bases of SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it

is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir., 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen large number of nucleic acids that have been modified because the result of such modifications is unpredictable. A nucleic acid sequence encodes the amino acid sequence, which determines the structural and functional properties of an enzyme. Applicants do not teach which 60% of SEQ ID NO:1 must be retained and which 40% of SEQ ID NO:1 can be modified and result in a functional β,β -carotene 15,15'-dioxygenase oxidase. Furthermore, applicants do not teach which 20 or 30 nucleic acids must be present in a DNA fragment for it to encode a functional β,β -carotene 15,15'-dioxygenase oxidase. Also, it is unpredictable whether a DNA fragment comprising 20 or 30 bases, which amount to about 1 % of SEQ ID NO:2, encodes a functional enzyme. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

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The specification, as discussed above, does not support the broad scope of the claims because the specification does **not** establish: (A) regions of the β,β -carotene 15,15'-dioxygenase oxidase structure which may be modified without effecting its activity; (B) the general tolerance to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Therefore, one of ordinary skill would require guidance, in order to make DNA or DNA fragments encoding β,β -carotene 15,15'-dioxygenase oxidase having 60 % homology to SEQ ID NO:1 or comprising 20 or 30 bases of SEQ ID NO:2 in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 8-9 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8-9, as written, recite a DNA fragment containing at least 20 or 30 nucleic acids of SEQ ID NO:2 with the limitations of claims 1 and 6. However, the claims are unclear because a DNA fragment of 20 bases, which roughly

equals to 7 amino acid residues, cannot encode an enzyme that is more than 60% identical to SEQ ID NO:1. Therefore, claims 8-9 have been interpreted as DNA fragments comprising 20 or 30 bases of SEQ ID NO:2 which encodes a polypeptide with β,β -carotene 15,15'-dioxygenase oxidase activity.

Claim 11 recites an antisense RNA. Claim 11 depends on claim 6 which comprises of nucleic acids encoding β,β -carotene 15,15'-dioxygenase oxidase. The claim is unclear because an antisense by definition does not encode a polypeptide but is complementary to a mRNA of a polypeptide.

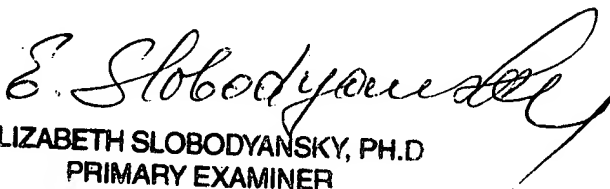
Claims 28-32 and 34-36 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4534.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner


ELIZABETH SLOBODYANSKY, PH.D
PRIMARY EXAMINER

January 30, 2001